DICHIARAZIONE DI CONFORMITÀ
DECLARATION OF CONFORMITY

La società KALTEK S.r.l. con sede legale e operativa in Via del Progresso n° 2 – 35127 Padova (Italia), dichiara sotto la propria totale responsabilità che i dispositivi medici denominati:
KALTEK S.r.l. with operating and legal head office in Via del Progresso No. 2 – 35127 Padova (Italy) certifies, on its own responsibility, that the medical devices named:

CONTENITORI PER CAMPIONI ISTOLOGICI
CONTAINERS FOR HISTOLOGICAL SAMPLES

(vedi dettaglio in allegato / see detailed attached list)

destinati ad essere impiegati come Dispositivi Medico-Diagnostici in vitro - Classe: altro
intended for use as In Vitro Diagnostic Medical Devices - Class: Others

- sono conformi ai requisiti essenziali indicati nell'Allegato I della Direttiva 98/79/CE del 27/10/98 (recepita con D. Lgs. n. 332 del 08/09/00 e ss.m.ii.), come da Fascicolo Tecnico n. FT 001KT/IVD (archiviato presso la Kaltek);
  comply with the requirements set out in the Annex I of the EC Directive 98/79 of 27/10/98 (enforced by the Decree No. 332 issued on 08/09/00 and its amendments and integrations), as described in the Technical File No. FT001KT/IVD (archived in Kaltek head office);

- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato III (escl. punto 6) della sopra citata direttiva;
  are manufactured according a quality system which complies with the requirements of the Annex III (except point 6) of the above mentioned directive.

Padova, 07/01/2020

kaltek srl
Il legale rappresentante
Cortelazzo Dr. Lorenzo

kaltek

ALLEGATO ALLA DICHIARAZIONE DI CONFORMITÀ
ANNEX TO THE DECLARATION OF CONFORMITY

COD./REF	DESCRIZIONE	DESCRIPTION
	TAPPO A VITE POLIPROPILENE	**SCREW CAP POLYPROPYLENE**
3705	30 ml	30 ml
3707	60 ml	60 ml
4969	90 ml	90 ml
5021	120 ml	120 ml
5022	160 ml	160 ml
5023	250 ml	250 ml
5024	500 ml	500 ml
5025	1000 ml	1000 ml
	CON SUPERFICIE DI SCRITTURA	**WITH MARKING AREA**
0157	150 ml	150 ml
2013	200 ml	200 ml
	CON ETICHETTA	**WITH LABEL**
4000	30 ml per formaldeide al 4%	30 ml for formaldehyde 4%
4300	60 ml per formaldeide al 4%	60 ml for formaldehyde 4%
4970	90 ml per formaldeide al 4%	90 ml for formaldehyde 4%
4600	60 ml per CYTOfast	60 ml for CYTOfast
2026	60 ml con paletta per formaldeide al 4%	60 ml with spoon for formaldehyde 4%
	TAPPO A VITE POLIETILENE ALTA DENSITA'	**SCREW CAP HIGH DENSITY POLYETHYLENE**
3210	5 ml	5 ml
3211	10 ml	10 ml
3212	30 ml	30 ml
3213	60 ml	60 ml
3214	90 ml	90 ml
3215	180 ml	180 ml
	CON SOTTOTAPPO	**WITH INNER STOPPER**
2434	50/60 ml	50/60 ml
0143	70 ml	70 ml
0144	120 ml	120 ml
0145	250 ml	250 ml
0146	500 ml	500 ml
0147	1000 ml	1000 ml
0148	2000 ml	2000 ml
	TAPPO A PRESSIONE POLIPROPILENE	**WITH PRESSURE CAP POLYPROPYLENE**
	SERIGRAFATO	**PRINTED**
0100	150 ml	150 ml
0101	250 ml	250 ml
0102	500 ml	500 ml
0103	1000 ml	1000 ml
0104	2000 ml	2000 ml
0106	3000 ml	3000 ml
0109	5000 ml	5000 ml
	TRASPARENTE	**TRANSPARENT**
3800	150 ml	150 ml
3801	250 ml	250 ml
3802	500 ml	500 ml
3803	1000 ml	1000 ml
3804	2000 ml	2000 ml
3806	3000 ml	3000 ml
3809	5000 ml	5000 ml
	CHIUSURA ERMETICA con etichetta	**HERMETIC CLOSURE with label**
0151	10 lt	10 lt
0152	17 lt	17 lt
0153	25 lt	25 lt
0149	21 lt	21 lt
	FORMA RETTANGOLARE con etichetta	**RECTANGULAR SHAPE with label**
0214	2500 ml	2500 ml
0212	5600 ml	5600 ml
0213	11000 ml	11000 ml
0252	17000 ml	17000 ml

	TAPPO A PRESSIONE POLISTIROLO	**PRESSURE CAP POLYSTYRENE**
0130	10 ml	10 ml
0131	20 ml	20 ml
0132	30 ml cf. 100 pz.	30 ml 100 pcs/box
0737	30 ml cf. 800 pz.	30 ml 800 pcs/box
0133	50 ml	50 ml
0134	75 ml	75 ml
0135	100 ml	100 ml
0136	150 ml	150 ml
0137	200 ml	200 ml
0138	250 ml	250 ml
0139	500 ml	500 ml
	TAPPO A PRESSIONE POLIETILENE ALTA DENSITA'	**PRESSURE CAP HIGH DENSITY POLYETHYLENE**
0597	1 ml	1 ml
3656	2,5 ml	2,5 ml
2014	5 ml	5 ml
3068	7 ml	7 ml
0437	25 ml	25 ml
3069	35 ml	35 ml
	CONTENITORE PER TISSUE VACUUM PLUS	**CONTAINER FOR TISSUE VACUUM PLUS**
3171	250 ml	250 ml
3172	500 ml	500 ml
3177	3000 ml	3000 ml
3179	5000 ml	5000 ml
	FILM A BARRIERA OSSIGENO - pellicola sigillante per contenitori Tissue Vacuum Plus	**OXIGEN BARRIER - sealing film for Tissue Vacuum Plus containers**
3175	140 x 270 mm	140 x 270 mm
3176	270 x 270 mm	270 x 270 mm
	CONTENITORE PER TISSUE FILLING EASY	**CONTAINER FOR TISSUE FILLING EASY**
3173	500 ml	500 ml
3176	1000 ml	1000 ml
3178	3000 ml	3000 ml
3180	5000 ml	5000 ml
	SACCHETTI VACUUM BAG per Tissue Vacuum	**VACUUM BAG for Tissue Vacuum**
3964	mm 550 x 340	mm 550 x 340
3963	mm 385 x 340	mm 385 x 340
4584	mm 300 x 250	mm 300 x 250
4585	mm 550 x 340 senza saldatura intermedia	mm 550 x 340 without middle sealing
0607	**CONTENITORE CONTAGLOBULI COULTER 35 ml**	**COULTER CUPS FOR CELLS COULTER 35 ml**
0670	**SECURE BOX contenitore per biopsie multiplo**	**SECURE BOX container for multiple biopsies**
2952	**ANTIDOPING TEST TUBE CON SIGILLLO**	**ANTIDOPING TEST TUBE WITH SEAL**
	BOTTIGLIA DIURESI 24 ORE	**24 HOURS URINE CONTAINER**
0405	Tipo tondo	Round shaped
0522	Tipo tondo in confezione singola	Round shaped single box
0406	Tipo leggero	Light plastic type
2294	A bauletto	Horizontal type
2537	A bauletto in confezione singola	Horizontal type single box
2373	Con manico in PE	With PE handle
2732	Tipo ovale	Oval shaped

Padova, 07/01/2020

kaltek srl
Il legale rappresentante
Cortelazzo Dr. Lorenzo

DICHIARAZIONE DI CONFORMITÀ - DECLARATION OF CONFORMITY

KALTEK S.r.l. su gamykla ir pagrindine buveine, esančia Via del Progresso, Nr. 2 - 35127 Paduva (Italija), prisiima atsakomybę, kad medicinos prietaisas pavadintas:

Universalūs konteineriai biologinių pavyzdžių saugojimui

skirtas naudoti kaip in vitro diagnostikos medicinos prietaisai - klasė: kiti.

- atitinka esminius ES direktyvos reikalavimus – 98/79/CE I priedas, 27/10/98, vykdomas pagal nutarimą Nr. 332 išleistą 2000-09-08 ir atitinka jo pakeitimai bei integracijos, kaip aprašyta techninėje byloje Nr. FT004KT / IVD (archyvuota Kaltek Pagrindinis biuras);

- yra pagamintas pagal kokybės sistemą, atitinkančią III priedo (išskyrus 6 punktą) reikalavimus.

Padova, 07/01/20

kaltek srl
Il legale rappresentante
Cortelazzo Dr. Lorenzo

DECLARATION OF EC CONFORMITY

WE:

Name of Manufacturer:
SOLAR

Limited Liability Company

UKRAINE, 36014 Poltava, Petra Doroshenka str. 57

EU Representative:
VARIA Ltd.

PRZEDSIEBIORSTWO Innowacyjno- Handlowe

POLAND, 60-473 Poznan, Biecka str. 10

Hereby declare, that the product:

Name of product: **Recording Thermal Papers for medical devices**
(ECG, EEG, CTG, videoprinters, spirometers, autoclaves, laboratory printers, defibrillators and other medical devices in which the recording thermal papers are used)

Product code: **aa x bb (aa x bb x cc)** It depends on dimension and format type

Classification
(per rule 1, Annex IX, 93/42/EEC): **Device of class "I"**

conforms to the MDD 93/42/EEC Council Directives

Applied harmonized standards, national
standards or other normative documents: EN ISO 9001:2009, PN-EN ISO 9001:2009, EN 980:2008, PN-EN 980: 2008, EN 1041:2008, PN-EN 1041:20120

Conformity assessment procedure: Annex VII point 3 of MDD 93/42/EEC Directive

Technical files at competent authority disposal

Poltava, 30-05-2019

"СОЛАР"
Ідентифікаційний код 32544823

REV07-062013v1.5

CE

ANNEX I to the Declaration of Conformity

aa x bb means size of roll paper: aa- width of the roll, bb- length of the roll
aa x bb x cc means size of Z- fold paper: aa- width of sheet, bb- length of sheet, cc- number of sheets in Z- fold

REV07-062013v1.5

CE

ATITIKTIES DEKLARACIJA

MES:

Gamintojas:
SOLAR

Įgaliota kompanija
UKRAINE, 36014 Poltava, Ostrovskogo 57

ES ATSTOVAS:
VARIA Ltd.

POLAND, 60-473 Poznan, Biecka str.10

Šiuo dokumentu deklaruojame, kad šie produktai:

Produkto pavadinimas:

Registracinis popierius mediciniams įrenginiams
(ECG,EEG, CTG, terminio popieriaus video printeriams, spirometrams ir kitiems medicininiams įrenginiams, kur naudojamas regstarcinis popierius).

Produkto kodas:

aa x bb (aa x bb x cc) Tai priklauso nuo dyžio ir formato tipo.

Klasifikacija
(taisyklė 1, Annex IX, 93/42,EEC):

I klasės produktas

atitinka MDD 93/42/EEC Tarybos Direktyvas

Taikomi standartai, nacionaliniai standartai ar kiti normatyviniai dokumentai:
EN ISO 9001:2009, PN-EN ISO 9001:2009, EN980:980:2008; PN-EN 980: 2008, EN 1041:2008, PN-EN 1041:20120

Atitiekties įvertinimo procedūra: Annex VII punktas 3 MDD 93/42/EEC Direktyva

Techniniai duomenys yra kompetentingų atstovų žinioje.

Poltava, 30-05-2019
/parašas/

CE

REV07-062013v1.5

Priedas prie atitikties deklaracijos

aa x bb atitinka dydį ruloniniam popieriui; aa -rulono plotis, bb -rulono ilgis
aa x bb x cc atitinka dydį knygutės tipo popieriui: aa -lapelio plotis, bb -lapelio ilgis, cc -lapelių skaičius knygutėje.

/parašas/

REV07-062013v1.5

Dokumentą elektroniniu parašu pasirašė AURELIJA POVILIONYTĖ-BERNATAVIČĖ
Data: 2023-03-14 11:08:43
Paskirtis: 648402
Vieta:
Energetikų g. 8, Kaunas
Kontaktinė informacija:
UAB Optinė riba 837451922